



Docket 17686 (OCU)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant: PATRICK M. HUGHES et al.	) Examiner:
	)
Serial Number: 10/826,441	)
	) Art Unit:
Filed: April 15, 2004	)
	) Confirmation No.:
For: STABILIZED BIODEGRADABLE	)
<u>NEUROTOXIN IMPLANT</u>	) Irvine, California

**INFORMATION DISCLOSURE STATEMENT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:


Applicant's provide with regard to the patent application entitled STABILIZED BIODEGRADABLE NEUROTOXIN IMPLANT, filed herewith one copy of documents of which they are aware, which may be material to the examination of this application, and in respect of which there may be a duty of disclosure under 37 C.F.R. §1.56. A listing of documents submitted is set forth on the attached Information Disclosure Citation (Form PTO-1449).

While these documents may be material pursuant to 37 C.F.R. §1.56, their disclosure is not intended to constitute an admission that the documents are prior art in regard to this invention. The filing of this Statement should not be construed to mean that a search has been conducted or that no other material documents or information exists. Please do not hesitate to contact the undersigned should any questions arise regarding this Statement.

The Commissioner is hereby authorized to charge any fees required or necessary for the filing, processing or entering of this paper or any of the enclosed papers, and to refund any overpayment, to deposit account 01-0885.

Respectfully submitted,

Date: June 30, 2004

  
Stephen Donovan  
Registration Number 33,433

Please direct all inquiries and correspondence to:

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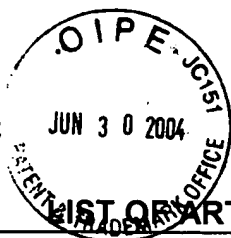
**CERTIFICATE OF EXPRESS MAIL UNDER 37 C.F.R. § 1.10**

I hereby certify that this Information Disclosure Statement and the documents referred to as enclosed herein are being deposited with the United States Postal Service on this date June \_\_, 2004, in an envelope as "Express Mail Post Office to Addressee" Mailing Label number EV193717099US addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Adriane Giberson  
Name of person mailing paper

  
Signature of person mailing paper

Date: June 30, 2004



**LIST OF ART CITED BY APPLICANT**

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<b>FILING DATE:</b> April 15, 2004	<b>GROUP:</b>

**U.S. PATENT DOCUMENTS**

*EXAMINER INITIAL		DOCUMENT NO.	DATE	NAME	CLASS	SUB-CLASS	FILING DATE (if applicable)
	AA	3,523,906					
	AB	3,691,090					
	AC	3,737,337					
	AD	4,389,330					
	AE	5,019,400					
	AF	5,989,545					
	AG	6,281,015					
	AH	6,506,399					
	AI						

**FOREIGN PATENT DOCUMENTS**

		DOCUMENT NO.	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION (yes/no)
	BA						
	BB						
	BC						
	BD						

**OTHER ART**

(Including Author, Title, Date, Pertinent Pages, etc.)

	CA	Aoki, K., <i>Preclinical update on BOTOX® (botulinum toxin type A)-purified neurotoxin complex relative to other botulinum neurotoxin preparations</i> , Eur J Neurol 1999 Nov; 6(Suppl 4);S3-S10
	CB	Bigalke H., et al., <i>Botulinum A Neurotoxin Inhibits Non-Cholinergic Synaptic Transmission in Mouse Spinal Cord Neurons in Culture</i> , Brain Research 360; 318-324:1985
	CC	Bigalke H., et al., <i>Tetanus Toxin and Botulinum A Toxin Inhibit Release and Uptake of Various Transmitters, as Studied with Particulate Preparations From Rat Brain and Spinal Cord</i> , Naunyn-Schmiedeberg's Arch Pharmacol 316; 244-251:1981

EXAMINER \_\_\_\_\_ DATE CONSIDERED \_\_\_\_\_

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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	CD	Coffield, J. et al., <i>The Site and Mechanism of Action of Botulinum Neurotoxin, Therapy With Botulinum Toxin</i> , Ed. Jankovic J. et al., Marcel Dekker, Inc., (1994), page 5
	CE	Gonelle-Gispert, C. et al., <i>SNAP-25a and -25b isoforms are both expressed in insulin-secreting cells and can function in insulin secretion</i> , Biochem J. (1999) 339:159-65
	CF	Habermann E., et al., <i>Tetanus Toxin and Botulinum A and C Neurotoxins Inhibit Noradrenaline Release From Cultured Mouse Brain</i> , J Neurochem 51 (2);522-527:1988
	CG	Habermann E., <i>Inhibition by Tetanus and Botulinum A Toxin of the Release of [<sup>3</sup>H]Noradrenaline and [<sup>3</sup>H]GABA From Rat Brain Homogenate</i> , Experientia 44 (1988); 224-226
	CH	Habermann E., <i>I-Labeled Neurotoxin from Clostridium Botulinum A: Preparation, Binding to Synaptosomes and Ascent to the Spinal Cord</i> , Naunyn-Schmiedeberg's Arch. Pharmacol. (1974) 281; 47-56
	CI	<i>Harrison's Principles of Internal Medicine</i> , edited by Anthony Fauci et al., 14.sup.th edition, published by McGraw Hill (1998)
	CJ	Marchese Ragona, R. et al., <i>Management of Parotid Sialoceles With Botulinum Toxin</i> , The Laryngoscope 109 (August 1999);1344-1346
	CK	<i>Movement Disorders</i> (1995), 10(3); 376
	CL	Naumann, M. et al., <i>Botulinum toxin type A in the treatment of focal, axillary and palmar hyperhidrosis and other hyperhidrotic conditions</i> , European J. Neurology (1999) 6 (Supp 4): S111-S115
	CM	Neimann et al., <i>Clostridial neurotoxins: new tools for dissecting exocytosis</i> , Trends in Cell Biol. 4 (May 1994);179-185
	CN	Pearce, L. B., <i>Pharmacologic Characterization of Botulinum Toxin For Basic Science and Medicine</i> , Toxicon (1997) 35(9); 1373-1412 at 1393
	CO	Sanchez-Prieto, J., et al., <i>Botulinum Toxin A Blocks Glutamate Exocytosis From Guinea Pig Cerebral Cortical Synaptosomes</i> , Eur J. Biochem (1987) 165;675-681
	CP	Schantz, E. J. et al, <i>Properties and Use of Botulinum Toxin and Other Microbial Neurotoxins in Medicine</i> , Microbiol Rev. (1992) 56; 80-99
	CQ	Singh, B., <i>Critical Aspects of Bacterial Protein Toxins</i> , pages 63-84 (chapter 4) of Natural Toxins II, edited by B. R. Singh et al., Plenum Press, New York (1996)

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	CR	Sloop, R. et al., <i>Reconstituted botulinum toxin type A does not lose potency in humans if it is refrozen or refrigerated for 2 weeks before use</i> , Neurology 48 (January 1997);249-53
	CS	Wiegand et al., <i>I-Labelled Botulinum A Neurotoxin: Pharmacokinetics in Cats after Intramuscular Injection</i> , Naunyn-Schmiedeberg's Arch. Pharmacol. 292 (1976); 161-165

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